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Unlocking the Secrets of Effective Sustained-Release Valsartan Tablets

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Abstract: ***Background:*** Valsartan is mostly recognized for the antihypertensive effects that it has. Biodegradable and harmless in their natural state, natural polymers also have fewer negative side effects. In contrast to synthetic polymers, it does not harm the environment and may be used without risk to humans. The focus of this effort was on developing sustained-release tablets of valsartan by the use of natural polymers such as guar gum and pectin. At the moment, the formulation of sustained-release tablets that include a matrix system is receiving a significant amount of attention. Formulation of sustained-release tablets of valsartan was accomplished by the use of the direct compression technique. The produced tablets were put through a variety of various pre-formulation tests before being put through *in-vitro* dissolving testing using a USP-III dissolution device. At 37^{0}Celsius, dissolution experiments of a variety of formulations were analyzed for 24 hours. The produced formulations, each of which had a different concentration of polymers (1:0.5, 1:1, and 1:1.5) respectively, were analyzed for a variety of physicochemical properties, and the findings of an *in-vitro* dissolution investigation showed that FG3 demonstrated superior drug release. As a result, the findings of the research indicate that FG3 might be an excellent option for the production of sustained release tablets of valsartan using natural polymers.

Keywords: Sustained release, Matrix tablets, Valsartan, Guar gum, Pectin, *In-vitro*, polymer, FG3.

INTRODUCTION

When it comes to several different medications, the fundamental objective of treatment is to attain a steady state blood or tissue level that is both effective in terms of therapeutic also nontoxic over a considerable amount of time [1-5].It is generally recommended to use a S.R. dosage form because of the following reasons: less variation of the drug in the body with good patient compliance; increase in impregnability margin of administration of drug; good drug absorption with less frequency of dosing; decrease in G.I.T. irritation due to the drug's local and systemic side effects; and good drug absorption with less frequency of dosing [6-10]. The accomplishment of the objective is significantly reliant on the conception of an appropriate shape. In the recent historical context, the C.R. notion has been getting a growing amount of attention towards the inability and toxicity of pharmacological substances when they are applied or allocated by standard methods of drug distribution [11-18]. As a

result, medications that are taken in the form of injectables, ointments, tablets, or capsules tend to cause fluctuations in the concentration of the drug in the systemic circulation, which results in ineffective toxicity and poor efficacy [19-25]. Hydrophilic polymeric matrix systems are used extensively in controlled drug delivery because of the reason as they simplify the process of achieving a good drug release profile, are economical, and have widespread support from the FDA[26-30].A controlled release drug delivery system is not only meant to slow down the rate at which the medication is distributed into the body, but it is also responsible for the repeatability and predictability of the rate at which drug substances are distributed [6]. Controlled release dosage forms may allow some degree of control over the time character of drug release in the body, as well as the spatial pattern of drug release, or both. A efficient and prolonged prolonged delivery of therapeutically effective dosages, localization of therapy, and patient comfortness are some of the important benefits that a sustained release dosage form may bring to us. These benefits can be appreciated when taking into consideration the factors of efficient and prolonged delivery [31-35]. The frequency of dosage may be reduced with the aid of an effectively designed S.R. drug delivery system, which in turn helps to keep drug concentrations stable in the systemic circulation. When the concentration of the medication drops below the minimum effective dosage level as a consequence of the fluctuations that occur in traditional drug administration, the outcome is a yield period that has a weaker therapeutic impact. By using a S.R. drug delivery system, it is possible to keep the drug concentration within a very narrow therapeutic range. This will result in a reduction in the severity of side effects and a reduction in the number of episodes [36-40]. In certain instances, the bioavailability of medication molecules to diseased tissue cells is controlled by a series of pharmacokinetics processes called release'-absorption, distribution, metabolism, and elimination. This sequence is responsible for the bioavailability of drug molecules. As a consequence of these processes, the medicine is not available to the cells of the target tissue in an effective manner [41-45].

The benefits of using formulations with continuous release [46-50]

- Strong ability to condense when patient
- Increased therapeutic efficacy
- Affordable from a financial standpoint
- Less variations in dosage • Correct place of action

Disadvantages of sustained release formulations include the possibility of overdosing, an increase in cost, and the possibility that an improper formulation might lead to an excessive dose or an inaccurate drug release.

Variables relating to pharmacodynamics and pharmacokinetics. The rate of absorption, the distribution of the medication, the biological half-life, and the metabolic conversion of the drug are all factors that are involved in the sustained release dosage form.

In formulations for sustained release, the function of the matrix system [52-55] makes use of hydrophobic as well as hydrophilic polymers in order to prolong the tablet's longevity and to extend the amount of time during which its medication release rate remains constant. Because of this, a significant amount of focus is presently being directed on the development of sustained-release tablets using matrix systems.

Since they have less negative consequences, natural polymers are often favored over synthetic ones in modern times.

Valsartan is a kind of drug that is classified as a BCS-II drug. It is an angiotensin II receptor antagonist, and it is often administered to patients suffering from high blood pressure or heart failure. It achieves its action by selectively inhibiting the vasoconstrictor and aldosterone-secreting effects of angiotensin II. This is accomplished by preventing the binding of angiotensin II and angiotensin I receptors in a variety of tissues [56-60].

MATERIAL AND METHODS:

Materials-

Pectin powder, Guar gum, Starch, Magnesium sterate and Sucrose were obtained from local market. Valsartan was obtained as a gift from MATS School of Pharmacy, MAS University, Aarang-Kharora Highway, Gullu, Arang, Raipur, Chhattisgarh, India.

Methods-

As a result of the use of natural polymers with various percentages of guar gum and pectin (1:0.5, 1:1, and 1:1.5, respectively), the formulation of Valsartan S.R. tablets has been processed using the direct compression technique. This has led to the exploitation of natural polymers. Prior to putting the components through sieve no. 10 and subjecting them to various post-compression inspections, we assigned each component a specific weight that accurately represented its own weight. This action started the series of examinations. For a length of time that might last up to twenty-four hours, an *in-vitro* dissolving study was carried out at a speed of 785 revolutions per minute, with a pH of 7.4 and 0.1 N hydrochloric acid to be used as the solvent. To explore the rate at which the drug was released, this was done for the goal of this. In addition to the FTIR spectra of the purified active pharmaceutical ingredient (Fig.3), a calibration curve was developed with a pH of 7.4 and 0.1 N hypochlorous acid (Fig.1, Fig.2). Each formulation contained thirty milligrams of valsartan, and the total weight of the manufactured product was one hundred fifty milligrams. Table 1 provides detailed information on this. [61].

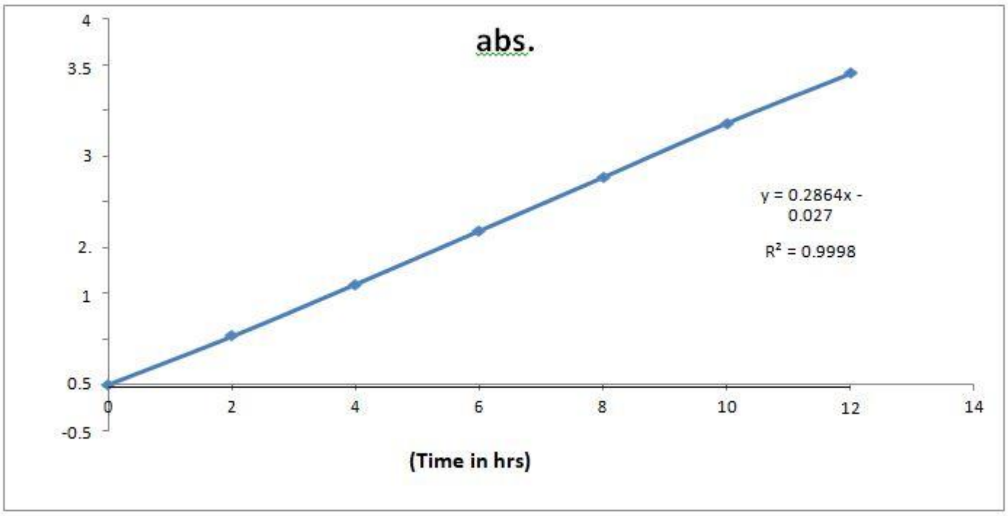

Fig.1: Calibration Curve of Valsartan Using 0.1N Hcl

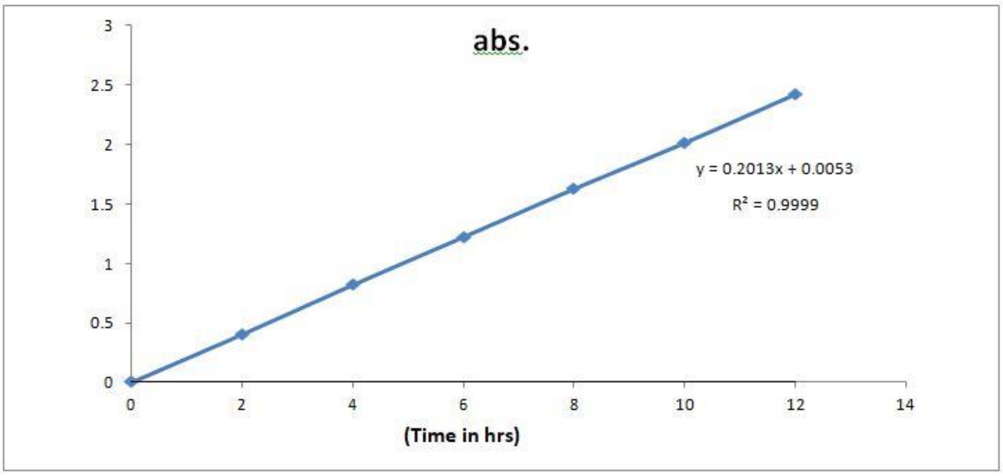

Fig 2: Calibration Curve of Valsartan Using pH 7.4

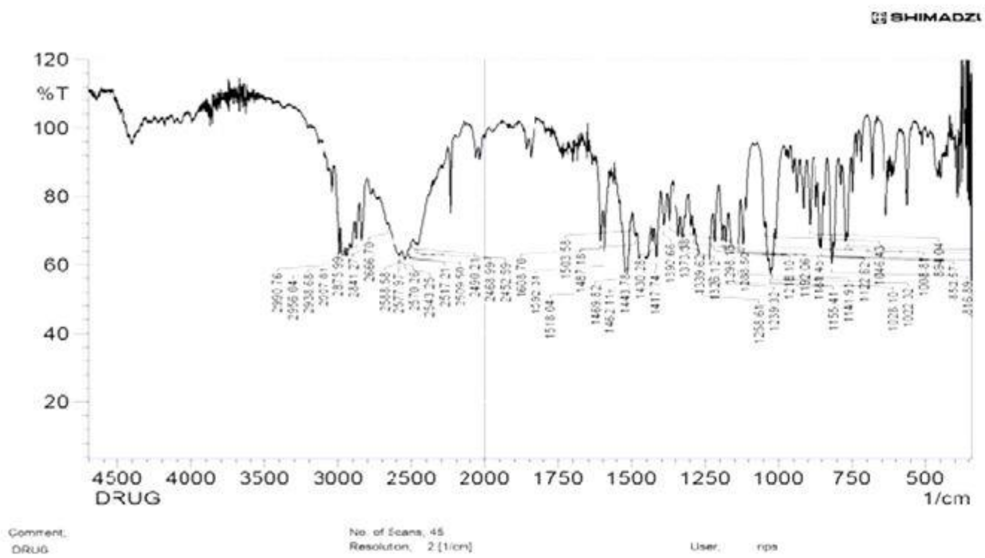

Fig. 3: FTIR Spectra of Pure Drug

Table-1: Formulation Table

Sl no	Ingredients	FG1 (mg)	FG2 (mg)	FG3 (mg)	FP4 (mg)	FP5 (mg)	FP6 (mg)
1	Valsartan	30	30	30	30	30	30
2	Pectin	-------	--------	-------	15	30	45
3	Guargum	15	30	45	-------	-------	-------
4	Mg sterate	2%	2%	2%	2%	2%	2%
5	Sucrose	101	86	71	101	86	71
6	Starch	3%	3%	3%	3%	3%	3%
	Total weight	150 mg	150 mg	150 mg	150 mg	150 mg	150 mg

RESULTS:

A large number of post-compression experiments were carried out, and each and every one of them arrived at the same conclusion: the limit that was established in Table 2 was not met. The *in-vitro* drug release activities of each of the several formulations are broken down in unambiguous detail in Fig. 4, which may be seen here.

Table-2: Evaluation Parameters

Sl no	Parameter	FG1	FG2	FG3	FP4	FP5	FP6
1	Hardness(kg/cm^2)	5.4	5.4	5.4	5.4	5.4	5.3
2	Swelling index(%)	0.023	0.036	0.052	0.023	0.041	0.062
3	Weight variation (%)	1.26±0.22	1.29±0.23	1.31±0.23	1.24±0.23	1.28±0.21	1.28±0.23
4	Drug content (%)	96	97.2	98.1	92.3	94.1	96.1

Table.3: Stability Data

Parameters	At initial day	After 30 days
Hardness (kg/cm2)	5.0±0.42	4.8±0.14
Thickness (mm)	3.52±0.64	3.52±0.11
Weight variation (mg)	400.04±4.87	399±0.78
Drug content (%)	101.01±0.2	99.97±0.7

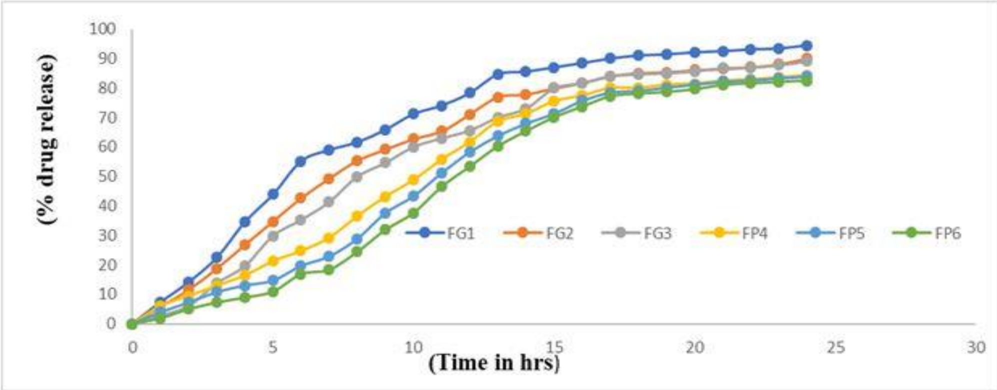

Fig.4: *In-vitro* Drug Release Research

DISCUSSION:

As compared to other formulations, it was discovered that FG3 allowed for a maximum drug release of 94.5 percent in only 23 hours, making it a preferable choice. So, further research has to be carried out or explored, and formulations containing natural polymers need to be produced and introduced into the market in order to lessen the severity of the adverse effects[62-68].

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Conflict of Interest: There is no conflict of interest.

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